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| 35811 | 7590 | 04/24/2008 | | |
| IP GROUP OF DLA PIPER US LLP | | | EXAMINER | |
| ONE LIBERTY PLACE | | | KIM, JENNIFER M | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|-------------------------------------------|
| Office Action Summary | Application No. 10/622,262 | Applicant(s) MAINNEMARE, ARNAUD |
| | Examiner Jennifer Kim | Art Unit 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 January 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 20-22 and 25-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 20,22,25-27 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1668)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

The amendment filed January 22, 2008 have been received and entered into the application.

Action Summary

The rejection of claims 20, 22, 25 and 26 under 35 U.S.C. 103(a) as being unpatentable over Julich et al. (1993) and Nagl et al. (1998) in view of Contreras et al. (1997) is being maintained for the reasons stated in the previous Office Action.

Applicant's amendment necessitated additional rejection presented in this Office action.

Response to Arguments

Applicant's arguments filed January 22, 2008 have been fully considered but they are not persuasive. Applicant argues that there was a long-felt need in the art for a treatment for patients with severe periodontitis that provided consistent results and that it had been found that a significant number of severe cases of periodontitis deteriorate over time with non-surgical treatment. This is not found persuasive because establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt

need and the failure of others to the issue of obviousness depend on several factors.

First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967) ("Since the alleged problem in this case was first recognized by appellants, and others apparently have not yet become aware of its existence, it goes without saying that there could not possibly be any evidence of either a long felt need in the . . . art for a solution to a problem of dubious existence or failure of others skilled in the art who unsuccessfully attempted to solve a problem of which they were not aware."); *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 217 USPQ 1281 (Fed.Cir. 1983) (Although the claimed invention achieved the desirable result of reducing inventories, there was no evidence of any prior unsuccessful attempts to do so.). **Second, the long-felt need must not have been satisfied by another before the invention by applicant.** *Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768, 9 USPQ2d1417, 1426 (Fed. Cir. 1988) (Although at one time there was a long-felt need for a "do-it-yourself" window shade material which was adjustable without the use of tools, a prior art product fulfilled the need by using a scored plastic material which could be torn. "[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved".) **Third, the invention must in fact satisfy the long-felt need.** *In re Cavanagh*, 436 F.2d 491, 168 USPQ 466 (CCPA 1971).

In this case, the long-felt need have not been satisfied by another **before** the invention by Applicant. It is noted that evidence provided Applicant (Claffey et al) is published after the filing date of the instant Application. Therefore, the long-felt need

has not been satisfy by another **before** the invention by Applicants. Moreover, the invention doesn't appear to satisfy the long-felt need because the "synergistic benefits" provided by Applicant (Mainnemare et al.) have been carefully considered and reviewed. However, it is not persuasive because typically the evidence submitted to establish unexpected synergism should compare each of the ingredients by themselves within the claimed composition in which the two ingredients are combined. Further, the amounts of each of the ingredients should be the same as the total amount of the ingredients combined in the claimed composition. In this case, there is no data showing each of the ingredients by themselves or the amounts. Therefore, it is not clear whether the results are actually unexpected. The applicant has the initial burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.06. Also, the claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "harmful molecules released from pathogens before and during their remove" and the term "physiology" lack literal support in the specification as originally filed.

This is a New Matter rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20, 22, 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Julich et al. (1993) of record and Nagl et al. (1998) in view of Contreras et al. (1997).

Julich et al. teaches that sodium hypochlorite (NaOCl) both have antiviral activity. (page 310, Table 3). Julich et al. teach that due NaOCl's excellent compatibility with various materials, it may be used for the disinfecting dentures. (page 311 right-hand side second full paragraph).

Nagl et al. teach that N-chlorotaurine is known to have bactericidal, fungicidal and vermicidal properties. Nagl et al. teach that N-chlorotaurine also demonstrated having virucidal activity including HSV-1 and 2. Nagl et al. teach that N-chlorotaurine in destruction of pathogens during inflammatory reactions and has application as an antiviral agent in human medicine. (abstract, table 1, page 27 under results).

Contreras et al. teach that herpesviruses have been implicated in the pathogenesis of human periodontitis. (abstract).

The claims differ from the cited references in claiming combination of NaOCl and N-chlorotaurine for the treatment of lesions and infections generated from periodontitis and herpesviridae, the mechanism of action of substantial stimulation of myeloperoxidase activity in the human or animal and the mechanism of action of neutralize harmful molecules and regulating the physiology of the immune system and healing tissue.

To employ combinations of NaOCl and N-chlorotaurine to treat lesions and infections generated from herpesviridae and periodontitis would have been obvious because all the components are well known individually for having virucidal activity (HSV) and bactericidal activity. It would be expected that the combination of components would treat infections generated from conditions involving bacteria or virus including peridonitis and herpesviridae as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Further, the treatment of lesions, and healing tissues and infections generated from periodontitis is obvious because herpesviruses have

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been implicated in the pathogenesis of human periodontitis as taught by Contreras. One would have been motivated to treat lesions, healing tissues and infection generated from periodontitis by employment of the obvious combination of NaOCl and N-chlorotaurine taught by Julich et al. and Nagl in order to achieve an expected additive benefit of antiviral activity. Moreover, the mechanism of action of without substantial stimulation of myeloperoxidase activity in the human or animal and neutralizing harmful molecules, regulating physiology of the immune system are all obviously achieved by the obvious modification involving same active agents for the same treatment.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
April 23, 2008